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14. ABSTRACT

The Valley Hospital of Ridgewood, New Jersey, is proposing to extend a limited but highly successful specimen management system. The system utilizes barcodes and handheld technology at the patient's bedside.
In addition The Valley Hospital looks to expand this success by implementing electronic medication administration and transfusion systems which function with the same technology as the specimen collection system.

15. SUBJECT TERMS
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INTRODUCTION

The program designed to reduce specimen collection, medication administration and transfusion errors at The Valley Hospital is rooted in utilization of bar-code technology in tandem with the use of handheld personal data terminals to create a positive identification system at the point of care. The purpose of this study is to examine active errors to determine the contribution of human and technological factors and ascertain if latent errors have been inadvertently introduced. Active errors will be measured by observing staff performing specimen collection, medication administration, and blood transfusion administration. Rule-based procedures have been developed to teach the staff correct processes for implementing the new technology. The rule-based procedure is a check list that sequentially lists each step needed to safely and appropriately complete the procedures.

BODY

The accomplishments of this research for the period of performance as defined in the statement of work are described herein. The specimen collection system was developed from its early testing stage as a PC unit based system with a uni-directional print stream interface to a central server based system. This included the development of bi-directional interfaces allowing for full integration with the hospital laboratory information system. In addition, a wireless backbone was installed in the hospital to allow for the transfer of real-time information flow. Over time, further hardware enhancements were made which enhanced speed of information flow and increased success on bar code scan rates.

One conversion was from palm pilots to pocket personal computers (PC) the other conversion was to update handheld printers which have blue tooth capability for wireless connection between the pocket PC and the printer. These hardware upgrades mainly facilitated the use of the wireless network installed in the hospital. As the technology was enhanced, the training and education program to teach users was developed as well. Through the study period over 1000 employees were trained and are using the system every day to collect clinical specimens. At the conclusion of the period of performance of this research, the specimen collection system is operational in all inpatient care areas of the hospital flowing over one million specimens through the system annually. Prior to

the implementation of the system the error rate ranged from 2- 2.2 % and the end of the research the error rate has been reduced to 0.025% or stated at a rate of accuracy as 99.975%.

During the period of performance in which this research was conducted, the following accomplishments were made regarding the installation and operation of the bedside medication verification system (BMV). The software was purchased and all the extensive but necessary dictionary building took place. A training program was developed intandum with the rule based procedure that is used for the observational part of this research.

One obstacle in the research identified early on by the software vendor was their inability to operate their software on a pocket PC. This meant that one piece of the research in this study could not be accomplished. The original plan included the observation of multiple processes being conducted by the clinician using one device. The next obstacle in the process of hardware selection was the variation of workspace considering that the hospital consists of three separate buildings each built in different decades and with very different space and layout designs. In the end, three different hardware choices were made to fit each unique building and workflow needs. Personal computers were installed in some patient rooms where space would permit. Computers mounted to moveable carts (COW) were utilized on other patient care units. With in the patient care units choosing COWs, some had secure medication storage in patient rooms and others utilized COWS that could accommodate a secure medication storage area. Another choice that was tested was electronic tablets (C-5 Tablets), this device was the closest to the pocket PC concept in that it was a handheld, self contained unit including a barcode scanner and PC. The wireless infrastructure that had been built allowed for the variety of choices in hardware.

The evolution and the availability of each of these hardware solutions drove much of the implementation plan.

At the end of the study, close to 700 registered nurses have been trained and are actively using the system to administer on average, 2 million doses of medication per year. The implementation of the BMV system was drawn out over the course of three years due to

the time it took to research viable hardware options for the system. This being said, the impact of the BMV system on latent medication errors has demonstrated a 50% reduction in errors.

The transfusion administration module presented the greatest number of challenges to the scope of work planned in this study. The software was received and dictionary building began and testing of the system took place. During this process it became evident that information was not flowing through the system as designed. The FDA passed a rule stating that each unit of blood is to have a barcode on it to distinguish it uniquely. The deadline has been changed several times causing units of blood for use to arrive without a barcode.

The software vendor's inability to operate their software on a pocket PC presented the same obstacle that was faced with the BMV project. The decision was made to utilize COWs as the hardware choice.

Identifying these limitations, the decision was made to test the system at the hospital's infusion unit in which the greatest number of blood transfusions take place. Further, it was decided that the system could only be effectively tested on the process when the unit of blood had a barcode. Given these constraints, the infusion staff's 12 registered nurses were trained to use the system and a total of 34 transfusions were observed using the system. It was agreed that the manual system that had been in place be done in parallel to the electronic scanning process.

The aim of this study in Phase II was to explore and understand latent and active errors that are generated from human interaction with technology processes. Validating the rule-based procedures will identify and eliminate the latent errors with the development of a standard of care that will maximize patient safety. Since practice patterns may have a wide variation depending on the specialty care unit, data was collected using direct observation procedures and during ongoing team rounds as the technology is implemented on each unit. The goal of these continued observations and team rounds was to determine if one universal rule-based procedure is appropriate or if customization is needed to ensure proper implementation of the technology. Should customization be required, specific clinical procedures would be written. The level of customization would be carefully examined as lack of standardization is known to introduce errors for staff

that work across many areas. The validated rule-based procedures will then function as protocols for use when the institution wide implementation of the electronic bar-coding system is completed for specimen collection, medication administration, and blood transfusion administration

KEY RESEARCH ACCOMPLISHMENTS

I. Technical Components

Specimen Collection System

Installed equipment and implemented the system in all remaining inpatient units and the Emergency Department.

System upgraded to support Pocket Personal Computers and wireless connections.

Developed a simulation training system

Developed Training Manual

Developed a functional Bi-directional interface between Meditech and the Specimen collection system

Maintenance and replacement (when necessary) of system equipment.

Beside Medication Verification System

Installed equipment and implemented the system in all inpatient units as well as the Emergency Department

Evaluated hardware options, laptops and C-5 Tablets

Developed a simulation training system

Developed a training manual

Transfusion Administration Module

Installed equipment and implemented the system on one patient care unit

Developed a simulation training system

Developed a training manual

Installed hardware and loaded software for the ISBT-128 barcode label producer in the Blood Bank.

II. Training Program

Specimen Collection System

- 676 RNs have been trained to use the system
- 158 Patient Care Associates have been trained to use the system
- 32 Business Associates have been trained to register and wristband patients for use with the system

Bedside Medication Verification System

- 676 RNs have been trained to use the system

Transfusion Administration Module

- 12 RNs have been trained to use the system

III. Human Use Protocol

- Approval of the human subject protocol by the USAMRMC to conduct research.
- 30 participants consented for the specimen collection system and a total of 130 observations of the process were conducted.
- 104 participants consented for the bedside medication verification system and a total of 284 observations of the process were conducted.
- 6 participants consented for the transfusion administration system and a total of 34 observations were conducted.

Reportable Outcomes

Specimen Collection System

Successful in-house and Emergency Dept implementation

Overall 1.1 million inpatient specimens collected annually through the electronic specimen collection system

Development and integration of a wireless real time network connection

Impact on latent specimen collection error revealed:

Prior to system implementation the error rate ranged from 2-2.2%

Post implementation the error rate is 0.025%. Re-stated as a rate of accuracy, 99.975% sustained over 1 year house-wide.

The system alleviated errors from the following sources: Patient Identification, wrong collection device type, and unlabeled or mislabeled specimens.

The observational study revealed that the user followed the steps as trained in the rule based procedure and demonstrated best practice with no recommendations for change. The enhancements made in the hardware, software and interfaces further validated the steps were necessary and in a sensible order. Some further software enhancements as a result of observations include: battery life icon, room/bed designation in the ED.

Observations:

118 out of 120 observed users followed the steps in the user scenario as trained

10 out of 120 observed users practiced a variation in the step of placing the label on the tube prior to collecting the next tube. This variation was only observed in the Emergency Department by patient care associates. The distribution of this process variation in the ED was statistically associated at a $P<0.05$.

One further opportunity for improvement in either the system design or in the rule based procedure is the failure in the step which allows the user to place the wrong label on the wrong tube however will be the correct patient.

Transfusion Administration Module

One patient care unit test completed over the course of 3 months.

The software was not mature enough to provide the safety measures through the entire transfusion process. It successfully provided a means to accurately identify the correct patient to the blood for transfusion. The results of our findings were forwarded to the

vendor, (Meditech) in order that they further develop the software to be a useful tool safely administering blood products to patients.

Not enough data was collected to have any statistical significance or determine impact on latent error in the process of blood transfusion.

Bedside Medication Verification

A failure in the study design was the inability to utilize one device for multiple processes since it was discovered that the software vendor could not support handheld technology. Wireless real time connection created an allowance to overcome the inability to not use hand held devices but enabled computer on wheels (COW) to be brought to the bedside. The study results showed a 50% reduction, sustained over 1 year. This reduction was in latent medication errors that had previously resulted from a failure in one of the "Five Rights" to safe medication administration, a language common to the registered nurse. The 5 Rights are; Patient, Drug, Dose, Route, Time.

The study explored age variation and if it had an impact on the user's ability to learn and adapt to the system. A measure of the degree of frustration the user was experiencing when using the system was also measured. Factors defined as sources of frustration would be the normal environmental factors that a user encounters every day.

The findings revealed a relationship between the age categories and the degree of frustration the user expressed while using the system.

The results are summarized as follows:

<35 ease of use, no factor of frustration due to external environment with use of the technology. Any display of frustration was explained by the participant as lack of their professional experience in caring for patients. The technology was one factor they could count on in making their work more organized.

35-45 High degree of frustration. The data capture showed the highest statistical association with this age group and their years of professional experience relative to the highest frustration rating.

45> low rate of frustration due external environment

A consistent pattern of medication errors was revealed during each unit go-live. During the go-live phase an increase in medication occurrences was noted and then a consistent drop

Observations # 284

100% followed steps in user scenario

Through the course of study the medication barcode scan failure rate went from a high of 20% to a low of 10% at the end of the study.

The study revealed that the rule based scenario reflected best practice and did not need changes.

A review of physician medication ordering patterns by nursing unit prior to the go-live was conducted. The findings were used in the following way:

Increased detail dictionary building included special instructions for administering certain medications. This was very helpful to the nurse. More detail order sets were built for use by physicians who made order details easier for the nurse to follow. Pharmacy purchased more pre-packaged drugs to increase success in scanning. Non-tethered oscillating laser scanners were purchased which improved the scan read rate on bar-codes. This increased user acceptance, decreased user frustration and increased scan read rates on bar codes. These interventions hastened the go-live period by 50% from approximately 12 weeks to 6 weeks.

DOD Final Report Conclusions

Specimen Collection Process

Users took part in the software design which enhanced ownership to use the system as designed.

Software design that makes sense to the end user, will be used as designed and not worked around.

Reducing a clinical process to as few steps as possible guided with the use of forcing functions at critical steps results in a system that is widely accepted by its users. This appears to transcend generational differences since the software design intuitively makes so much sense to the user that any workaround only results in complexity. Hence the workaround is abandoned and acceptance of the electronic process is adopted by the user. The researcher believes the proof of this hypothesis is revealed in the error rate of 0.05% at the end of this study. Conversely, the one step that allows the user to make a choice as to when they affix the label on the specimen container reveals the one remaining source for error.

Transfusion Module

Complete software needs to be written, tested prior to implementation.

Bedside Medication Verification System

Reduction of medication errors as a result of a failure of one of the "5 Rights" to safe medication by 50%

Training and Implementation

Training on the computerized clinical system must be sensitive to age or generational categories.

Observation of the 35-45 year old group revealed that the computer slowed them and made them inefficient. The Generation X employee, typically between the ages of 25-45, make up approximately 22% of the healthcare workforce. Some of their characteristics developed as they watched their boomer parents, be workaholic loyal employees, then to be let go by their companies. Generation X people were typically latchkey kids,

developed a great sense of self sufficiency. Their characteristics are self reliant, survivor mentality, wanting a balanced life. They grew up with information technology and multitask as a norm.
The researcher submits that there may be two subsets in this generational group since technology has advanced so fast during this generation's development. Those under 35 are the most accepting and reliant on computer technology and welcome each latest feature on a new device.

The 35-45 group have embraced technology because they were introduced early enough in their development to recognize and incorporate the technology in assisting their self reliance however not enough to develop over reliance on it.
Observation of the 45 and older group revealed they accepted the technology as an assist and appreciated in that intent. Those in the 45 and older would be considered baby boomers and make up approximately 53% of the healthcare workforce. Characteristics used to describe baby boomers are, interest in learning new skills, workaholics, interested in participation and spirit in the workplace, loyal employees.

Integrating the philosophic perspective with the technology safety advantages and valuing their co-existence.
The stronger example of the successful co-existence of technology with clinical practice is in the specimen collection process. We had more opportunity to influence software design by working closely with the vendor as a development site than we did with the vendor of the bedside medication verification system. The influence resulted in a technology process design that aligned most closely with the caregiver's thought process. This resulted in few workarounds and a very high rate of success, (99.975% accuracy).

The recognition that one solution isn't the answer for all was tried during the hardware application discovery. The combined factors of physical plant differences, the vendors' limited ability to operate their software on numerous types of hardware platforms during this study's period of performance and the varied preferences of the clinical workforce to

different hardware choices have made this a complex issue. This discussion is relative to the ever evolving advances in hardware choices coming to the market.
Through the study period it appears that user preference is turning toward the PC over the handheld devices due to increased visibility on the screen, a larger keyboard facilitates easier typing and mounted on carts make them mobile.
The addition of wireless scanners in use with the COWs have increased scanning success rates as well as reduced user frustration.

Perhaps the most compelling finding of all in this research is user acceptance of the system which yields the greatest results in error reduction or safest practice for patients. This appears to hold true when there is simplicity of process design as influenced by the end users input and guided by forcing functions at the most critical steps in a process.

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Appendix 1

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Present Position:

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Director of Clinical Systems Quality Improvement
The Valley Hospital
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Prior Experience:

Assistant Director of Pharmacy
The Valley Hospital
Ridgewood, New Jersey (1985-2000)

Accomplishments:

Chairman of the Performance Improvement Committee of the NJHA,
Quality Institute

Member of the Technology Committee of the NJHA, Quality Institute

Managing the operations and clinical performance of a progressive pharmaceutical service

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Member of the Patient Safety and Quality Committee
Board of Trustees at The Valley Hospital

Member of the Quality Improvement Advisory Board, The Department of Health, State of New Jersey. Appointed by the Commissioner of Health, State of New Jersey

Presentations:

"Partnering With Your Patients- A Way to Reduce Patient Identification Errors," Institute for Healthcare Improvement National Congress, 5/96

"A Hospital's Working Model of a Medication Management System," ASHP Annual Meeting 6/2000, ASHP Midyear meeting 12/2000.

"Reducing Specimen and Medication Error with Hand-held Technology,"
Health Information Management and Systems Society 2001 Annual Conference, 2/2001

"Patient Safety, One Hospital's System-wide Approach to Reducing Medical Errors," Joint Commission 2001 National Conference, 11/01

Publications:

Mutter M., Bologna L., Hardy G., "Reducing Specimen and Medication Error
With Hand-held Technology," Health Information Management And Systems Society. Winter 2002, 16:1: 65-70.

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Education:

Masters of Science in Management
New Jersey Institute of Technology, May 1995

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Appendix 2

List of Personnel

Name	Role
Michael Mutter	Principle Investigator
Daniel Baker	Information Systems Help Desk
Arceli Baluyot	Information Systems Analyst Lab
Barbara Dolan	Information Systems Analyst RN
Elizabeth Emery	Information Systems Help Desk
Susan Gehringer	Clinical Educator RN
Beth Hartog	Blood Bank Coordinator
John Heeren	Information Systems Analyst RP
Bridgette Lee	Information Systems Help Desk
Michelle Naylor	Blood Bank Manager
Eric Rogers	Information systems Analyst
Claudine Roseicki	Clinical Educator RN
Sean Samiljian	Information Systems Analyst
Melissa Varela	Patient Safety Analyst RN
Susan Willey	Clinical Analyst RN

Appendix 3

Manuscript

Background

Medical errors are a significant cause of morbidity and mortality among hospitalized patients (Kohn, Corrigan and Donaldson, 2000; Leape, Brennan and Laird, 1991; Thomas, Studdert, Burstin, et al., 1999). The costs of these errors, although difficult to track, result in a major financial burden on the healthcare system (United States Department of Health and Human Services, 2003). These cost results from increased length of stay, increased care needs, staff time, and legal fees (Bates, et al. 2001; Brennan, Leape and Laird, 2001).

Specimen collections, medication administration, and administration of blood products are three high-volume procedures, consistently conducted in hospitals that greatly contribute to the medical error rate (Kohn, Corrigan and Donaldson, 2000; Leape, Brennan and Laird, 1991; Thomas, Studdert, Burstin, et al., 1999). The variety of errors that arise from these procedures requires a systematic approach that automates routine processes and reduces human interactions and decision-making (Doug, 2003; Nichols, et al., 2004). Galusha, et al. (2002) suggested (extrapolated) from the literature that for a typical 300-bed hospital, more than 40 potential and preventable adverse events (ADEs) occur every day. Electronic bar-coding systems reduce errors from human intervention, are highly accurate, and are universally reported to significantly decrease error rates (Bridge Medical, Inc, 2002; Galusha, 2003; Johnson, 2002; Douglas, 2003; Neuenschwander, et al.,2003; Nichols, et al., 2004; Work, 2005). Because patient bands can encode demographics including name, medical record number, age, bed, and billing information, bar-coding enables accurate patient identification and an electronic method to track the processes involved in specimen collections, medication administration, and administration of blood transfusions (Nichols, et al., 2004).

Neuenschwander, et al. (2003) reported that by bar-coding patient identification bands and medication doses, facilities can reportedly reduce medication errors by 65 to 86 percent. Veterans Administration Hospitals have demonstrated that this is a real-time

solution to validating bedside medication administration when they implemented bar-code medication administration software in all of their 163 hospitals in 2000 (Johnson, et al., 2002). For medication administration, the bar-code system validates the accuracy of the medication or warns of a potential error if the action does not meet the five rights of safe medication administration practice (right patient, right medication, right route, right dose, and right time) (Johnson, et al., 2002; FDA, 2003; Galusha, 2003; Work, 2004) at the point of administration

The Food and Drug Administration (Sazama, 1990) reported mis-transfusion as the leading cause of death, from the time reporting began in 1976 through 1985; however, the FDA only requires national reporting of fatalities, so data on the full range of serious adverse events is most likely underreported. Transfusion of blood to the wrong patient (mis-transfusion) is the most serious hazard of transfusion and typically results from an error made during the bedside check just prior to transfusions (Dzik, 2002; Sazama, 1990). In fact, the single most important factor in wrong blood transfusion incidents is misidentification of the patient during the transfusion process (Wald, 2001). Despite technical improvements in testing for blood group identification, fatal ABO-incompatible transfusions in the U.S. continue to occur at a rate ranging from approximately 1:600,000 to 1:800,000, with as many as two dozen fatalities in the U.S. annually.

The Valley Hospital (TVH) Experience

In 1997, TVH decentralized the Phlebotomy Department. The error rate increased and these errors were defined as: patient misidentification errors, specimen non-labeling or mislabeling errors, inability to decipher illegible handwriting, and blood bank labeling errors. The Patient Safety Steering Committee noted that because this resulted in more caregivers involved in patient draws outside of the lab environment, errors could no longer be traced to specific individuals.

Consistent with the emerging data supporting the use of electronic bar-coding to decrease medical errors, and to comply with the FDA requirement to label all drug and biologic products (Federal Drug Administration [FDA], Department of Health and

Human Services, 2004), TVH acting as a beta site (Phase I), implemented the electronic bar-coding system for specimen collection. The bar-coding system was implemented on 10 units and pre- and post-implementation analysis showed a significant reduction in the number of specimen collection errors. (Bologna, Mutter and Hardy, 2001). TVH, was also a beta site for the development of rule-based procedures for use when implementing the electronic system for medication administration on a medical surgical unit. An additional aim of this pilot was to determine the feasibility of implementing this system institution wide for medication administration. The medication administration process was observed over time. The data were used to develop software to list steps of the medication administration process. This rule-based procedure was then tested to determine how well the user could function following these steps. Modifications were made based on data generated recommendations.

Regarding blood transfusion administration, an analysis of occurrence reports related to blood transfusion administration revealed the following critical process failures: patient identification, labeling and match for the correct unit of blood. The present rate of error is 0.012. This rate is pre-implementation of the electronic bar-coding system for transfusion administration.

An aim of the present study (Phase II) was to continue this work by implementing the electronic bar-coding systems institution wide for specimen collection, medication administration, and blood transfusion administration. In addition, the Meditech bedside medication verification system for medication administration was implemented and the rule-based procedure specific to each of these processes in different clinical areas was refined and validated. In March of 2003, the Food and Drug Administration (FDA) proposed two rules to improve patient safety: medication bar-coding and safety reporting. The current plan was to implement electronic bar-coding institution wide, while simultaneously refining and validating the rule-based procedures specific to each process.

Technology Problem

A recent study showed that members of the healthcare team resort to manual entry if they become frustrated in attempting to get the electronic bar-coding devices to scan (Nichols, et al., 2004). Nichols, et al. (2004) investigated the sources of bar-code scanner failure between two point-of-care testing devices and reported that both were failing to read the bar-codes on every attempt and this led to staff resorting to manual entry, increasing associated errors. Scanner failure rates were found to be dependent on the device, bar-code and for some bar-codes, the operator. New bands and operator identification badges were significantly more successful than worn bands to scan. Nichols, et al. (2004) point out that other possible effects, such as moisture, blood stains and other factors can lead to bar-code scanner failure. Development of workarounds resulting from the unreliability of technology can result in errors (Heinen, Coyle and Hamilton, 2003). Nichols, et al. (2004) caution that institutions must seek to understand the limitations of scanners to realistically address them, or clinical operators of electronic bar-coding systems will not be able to meet the expectations to adopt the appropriate technique for scanning. TVH has a de-centralized admission process and provides wristband printers on each nursing unit. Wristbands are reproduced as needed. The number of times that the user has to attempt to scan the wristband was tracked in the present study.

Objectives

Within hospitals, the diagnosis and management of medical and surgical procedures involves specimen collections, medication administration, and administration of blood transfusions. The processes employed to accomplish these activities are complex and create the potential for medical errors (Kohn, Corrigan and Donaldson, 2000; Leape, Brennan and Laird, 1991; Patterson, Render, and Ebright, 2004; Thomas, Studdert, Burstin, et al., 1999). A latent error occurs when the individuals designing the systems introduce flaws. Active errors result from individuals attempting to complete tasks using the poorly designed systems. Latent errors are also referred to as blunt end errors as they occur away from the actual work while the active errors are called sharp

end errors as they occur at the final point of where the work is being performed. Individuals writing the procedures to implement the new technology work at the blunt end while the staff that operates the technology works at the sharp end. Electronic point-of-care systems have significantly decreased sharp end medical errors (Bologna, Mutter and Hardy, 2001; Douglas, 2003; Galusha, Brown and Kelly, 2003; Johnson, Carson, Tucker and Willette, 2002; Work, 2004); however, there is a need to examine what Bates, et al. (2001) terms the "unknown, unknown" routes of error that can result from this new technology (p. 301). These are errors that we are not yet aware of, that have the potential to be generated by information technology (Heinen, Coyle and Hamilton, 2003; Nichols, et al., 2004; Wald, 2001).

The electronic bar-code systems for specimen collection was initially implemented in the Emergency Department and the rule-based procedure specific to specimen collection was piloted at that time. The Emergency Department has been recommended as a site to study errors (Croskerry and Sinclair, 2001; Croskerry, 2005), because of clinical complexity and time pressured decision-making in a highly distractible environment. Interruptions and distractions are well-known causes of active errors (Reason, 1990) and predispose the staff to errors that are related to human factors (Croskerry, 2005). Implementing new technology systems in this type of an environment may introduce unintended errors (Bates, et al., 2001; Heinen, Coyle and Hamilton, 2003; Nichols, et al., 2004; Wald and Shojania, 2001). Implementation of the bar-code system for specimen collection then progressed to three critical care units, and then hospital wide. The bar-code system for medication administration was implemented on a medical geriatric unit and a medical cardiology unit, and then progressed house wide. The bar-code system for blood transfusion administration was implemented on a medical oncology infusion unit.

The aim of this study was to explore and understand latent and active errors that are generated from human interaction with technology processes. Validating the rule-based procedures were used to identify and eliminate the latent errors with the development of a standard of care that maximized patient safety. Since practice patterns

varied widely depending on the specialty care unit, data were collected using direct observation procedures and during ongoing team rounds as the technology was implemented on each unit. The goal of these continued observations and team rounds was to determine if one universal rule-based procedure was appropriate or if customization was needed to ensure proper implementation of the technology. When customization was required, specific clinical procedures were written. The level of customization was carefully examined, as lack of standardization is known to introduce errors for staff that work across many areas. The team was composed of the interdisciplinary team that was involved with each of the processes. The validated rule-based procedures functioned as protocols for use when the institution wide implementation of the electronic bar-coding system was completed for specimen collection, medication administration, and blood transfusion administration. The Meditech bedside verification system was also used for medication administration.

The objectives of this study were to:

1. Analyze the rates and types of latent and active errors using bar-code technology for specimen collection, medication administration, and blood transfusion.
2. Correct latent errors introduced with the rule-based procedures for: specimen collection, medication administration, and blood transfusion administration.
3. Understand the human interaction with the technology and the impact on workflow processes.
4. Develop a "best practice" rule-based procedure to eliminate errors resulting from non-standardized use of the equipment.
5. Determine if customization of the rule-based procedures is needed in diverse clinical settings to successfully implement the technology.
6. Analyze the rates and types of latent and active errors using bar-code technology for specimen collection, medication administration, and blood transfusion.
7. Expand the knowledge about latent errors with bar-code technology to provide support to other healthcare facilities wishing to implement this technology.
8. Provide feedback to manufacturers and the FDA about problems identified with the hardware and software.

From these objectives which were derived from the literature, the following research questions flowed:

1. What is the active error rate in specimen collection?
2. What variables influence (predict) active error rate in specimen collection?
3. What is the active error rate in medication administration?

4. What variables influence (predict) active error rate in medication administration?
5. What is the active error reduction rate in blood transfusion?
6. What variables influence (predict) active error rate in medication administration?
7. Is there a difference in active error rates for blood administration, specimen collection and medication administration in different clinical areas?
8. Are there variables that predict active errors that are common to the three processes: medication administration, specimen collection, and blood transfusion?
9. What is the time to administer medications after bar-code technology implementation? Is it technically possible to meet regulatory mandates to administer medications within the 60 minutes window?
10. How does the latent error rate for specimen collection, medication administration, and blood transfusion administration differ pre- and post-technology implementation?

The Method

Design

A multi-method descriptive design was used to examine factors that are associated with latent errors while implementing electronic bar-coding institution wide. This multi-method descriptive design included data collection during structured direct observations, using qualitative field notes embedded in quantitative surveys (rule-based procedures) specific for each process to examine latent error rates, and to understand how human factors and technology factors can generate these errors.

Data were collected by way of structured rule-based procedures developed during Phase I of this project (See Tables 1-3). The rule-based procedure is a check list that sequentially lists each step needed to safely and appropriately complete each process: specimen collection, medication administration, and blood transfusion administration. The rule-based procedure was used by the Study team to directly observe the individual who was performing the process. The Study team member checked off each step as it was being performed (or note otherwise). In addition, human factors, technologic factors, and environmental factors that could influence latent errors were noted. If the nurse deviated from the rule-based procedure, then she/he was encouraged to verbalize the reason for changing the process in an attempt to identify latent errors.

Sample

The study was designed to have a sample size of forty-five employees including nurses and patient care associates to be enrolled in the study. This allowed for approximately 15 employees for specimen collection type observation, 15 for medication administration type observation and 15 for blood administration type observation. Employees were considered enrolled when they sign the informed consent document and participants when they are observed by the study team. Because of the multi-method design of this study, the qualitative portion involving the observation of the volunteer employee precludes citing an exact N of subjects for the study. The total N was determined by the number of observations necessary to reach "saturation" i.e., when the data from the direct observations have become repetitive are not providing any new information and when the PI has validated the paper protocol. A series of three observations were performed on each participant. When new information was noted during any of the three observations, another series of observations was conducted. This procedure was repeated until saturation was reached. Therefore, the key point in this phase of the process was that saturation of the data occurred, that is, the observations became repetitive and were not providing any new information. This method has been successfully used to examine how procedures are followed when employees use technology (Crayon, et al., 2004; Patterson, Cook and Render 2002).

The approximation used to determine the number of subjects above was based on previous efforts at The Valley Hospital by the same PI to determine and validate processes in this same manner. However, it is recognized that the total sample might have ultimately been higher or lower than this number, since it was dependant on the findings that accumulated while the observations were being done. Observations from the subjects were used to validate the protocols and no further statistical testing was undertaken with these data.

Inclusion/Exclusion Criteria

Employees who were invited to participate in the study included all Valley Hospital employees having a competency in and job description for the task involved (specimen collection, medication administration, blood administration), and who were working on the units that used electronic bar-coding. Consistent with the findings of Crayon, et.al. (2004), when accruing subjects for observation methodology, supervisors were asked to leave the room. Employees who met the criteria and sign consent were enrolled regardless of age, race, sex, pregnancy, or any other factor. Employees who were excluded from the study were those who did not perform specimen collection, medication administration, or blood administration as part of their job description and competency level, and those who did not sign consent.

Direct Observation

Data were collected using structured direct observation with the rule-based procedure to determine if the identified steps were accurate to successfully complete a safe and appropriate process when collecting specimens, administering medication, or administering blood products. Direct observation is a method used successfully by investigators to collect data on human factors and technology factors that influence latent and active error rates (Carayon, et al., 2004). One observer conducted all of the direct observations.

The observer was a nurse who was knowledgeable about clinical processes and the bar-coding software. This approach met the recommended requirements of a direct observer (Carayon, et al., 2004). In addition, Carayon, et al. (2004) recommends that, when feasible, both a human factors engineering expert and a pharmacist participate. In the present study, concepts derived from human factors engineering and the literature on electronic point of care technology was included in the rule-based procedure to keep the observer mindful of these issues. Lobiondo-Wood and Haber (2002) caution that during observation, the observer may miss information because of bias, lack of knowledge, values and emotions. Another limitation of the direct observation methodology of data collection is threat of the Hawthorne effect (Lobiondo-Wood and Haber, p. 168, 2002) i.e., the staff may respond to the observer, not because of the rule-based procedure but

because she/he is being studied. To minimize these limitations, the observer participated in several self-training and dry runs in a setting that resembled the environment that was the focus of the actual observations (Polit and Hungler, 2005). During these dry runs, facial expressions and body language were critiqued by a Quality Assurance Coordinator with research experience, until the observer felt confident that she/he was as "bias free" as possible. In addition, the observer was instructed to view procedural deviations as a positive finding that may identify latent errors and not to correct the user but rather to allow the user to continue uninterrupted (as long as this did not generate an error). Participants were told that the purpose of the study was to identify the best way to use this technology and that her/his ideas about how to improve processes were most welcome. It was hoped that this approach would offset staff ideas that blindly following the rule-based procedures were the desired outcome.

Saturation was considered complete if no new information was identified from any one of the direct observations. In the event that new information was noted, an additional three direct observations were completed. This process was repeated until saturation was reached (Carayon, et al. 2004).

Procedure Followed

1. Scheduled observation time with the unit manager.
2. Confirmed time with the nurse manager the day before the observation was scheduled.
3. Met with the employee who was to be observed.
4. Reviewed observation procedure with employee including asking the participant to provide feedback about concerns, issues or negative feedback.
5. Location chosen that provided distance, but allowed for unobstructed viewing.
6. Completed check list and notes during observation.
7. Informed staff member when observation was complete and asked clarifying questions at the time (e.g., if the participant deviated from the rule-based procedure, observer needed to clarify the rationale for the change).
8. Completed notes directly after observation.

Review of Occurrence Reports

Documented specimen collection errors, medication administration errors and blood transfusion errors were compared pre- and post-implementation of the electronic

bar-coding system. Medication administration error rates were calculated per 10,000 doses of medications dispensed. Specimen collection error rates were calculated by total transfusions administered month to month. Pre- and post-implementation data were collected during the same months to control for seasonal variation in practice that could have influenced rates.

Rule-Based Procedure

The rule-based procedure is a document commonly used in Information Technology Systems design and development during the Requirements Definition phase, when one is validating whether a user is interacting with a technology system in accordance with the desired process required or desired. It also acts as a protocol in that it prescribes a detailed series of actions and steps that the user is taking. The rule-based procedure data collection tool was developed based on clinical observation and a review of the literature (Carayon, et al., 2004). Content validity of each of the tools was supported with 100 percent agreement among the clinical team (Quality Assurance Manager of Blood Bank and Laboratory Quality Assurance, Nurse Director of Performance Improvement Home Care, Nurse Researcher and Coordinator of Quality Assurance, nursing staff, phlebotomists, patient care associates).

The rule-based procedure consisted of three parts. The first part includes demographic/descriptive categorical data: staff category, age, years of professional experience, years of experience at The Valley Hospital, educational level, nursing unit, staff ratio; the second part included environmental factors categorized as yes or no; good lighting, quiet, station/site condition uncluttered, and the third part included the start and end time of the procedure and each step of the process in sequential order, so that the observer could easily check off the occurrence of each step (See Tables 1-3)

Table 1 - Rule-Based Procedure: Specimen Collection

User Demographics		
Employee involved: Patient Care Associate / Registered Nurse		
Age	Years of professional experience	Years of experience at Valley Hospital
Educational level	Nursing unit	Staff ratio
Goal: Obtain the correct specimen collection information for a specific patient and for the group of patient specimen collection population for the shift; create the correct labels using the bar-coding procedure of the system; identify the correct patient and match collection equipment and procedures using the bar-coding system; collect and process specimen properly and document specimen collection and processing procedures.		

Specific Goal	
Step #	**Action**
1	Log onto the system by scanning the user ID badge with PDT
2	Select patient rooms for collection
3	Re-dock PDT into cradle to upload patient orders
4	Collect phlebotomy supplies and select a patient on the PDT list
5	Scan the patient wristband - confirm positive patient ID - at the bedside
6	Collect the specimens according to the order on the PDT
7	Scan the tube type bar-code on the specimen container
8	Information is passed from the PDT to the portable printer
9	Bar-code accession labels are printed on the portable printer
10	Labels are taken from the printer and applied to the primary tubes
11	Primary tubes are prepared for transport and sent to the lab
12	PDT is docked into the cradle uploading all collection
13	Caregiver ID, collection date and collection time are uploaded into the laboratory information system
14	Environment: Well lit
15	Environment: Free from clutter
16	Environment: Quiet
17	Human Factors: Interruption
18	Human factors: Distractions
19	Human Factors: Multitasking
20	Human Factors: Organizational skill
21	Human Factors: Followed workflow process
22	Cognitive Factors: Emotional variables
23	Cognitive Factors: Familiarity/certainty
24	Cognitive Factors: Bias (preconceived notions)

Table 2 - Rule-Based Procedure: Medication administration Process

User Demographics		
Employee involved: Patient Care Associate / Registered Nurse		
Age	Years of professional experience	Years of experience at Valley Hospital
Educational level	Nursing unit	Staff ratio
Goal: Obtain the correct medication administration information for a specific patient and for the group of patient receiving medication for the shift; identify the correct patient; choose the correct medication, dose route and the correct administration time using the bar-coding system; collect and administer medication properly and document medication administration process procedures.		

Specific Goal	
Step #	**Action**
1	Log onto the system by scanning the user ID badge with PDT
2	Select patient for medication to be administered
3	Collect medication doses to be administered
4	Scan the patient wristband to confirm positive patient ID at the bedside
5	Scan chosen dose of medication
6	Note any lab value that may impact the administration of the dose
7	Document any vital sign that may impact the administration of a medicine into the handheld device.
8	Note the time of the dose being administered relative to the scheduled time.
9	The session is closed by pressing the filing button
10	Environment: Well lit
11	Environment: Free from clutter
12	Environment: Quiet
13	Cognitive Factors: Emotional variables
14	Cognitive Factors: Familiarity/certainty
15	Cognitive Factors: Bias (preconceived notions)
16	Human factors: Interruption
17	Human Factors: Distraction
18	Human Factors: Multitasking
19	Human Factors: Organizational skill
20	Human Factors: Followed workflow process

Table 3 - Rule-Based Procedure- Blood Transfusion

User Demographics		
Employee involved: Patient Care Associate / Registered Nurse		
Age	Years of professional experience	Years of experience at Valley Hospital
Educational level	Nursing unit	Staff ratio
Goal: Obtain the correct transfusion process information and for the group of patient transfusion population for the shift; using the Hollister labeling system and identify the correct patient matching the correct blood product and properly administer and document the transfusion process.		
Specific Goal		
Step #	**Action**	
1	Log onto the system by scanning the user ID badge with PDT	
2	Select patient rooms for collection	
3	Re-dock PDT into cradle to upload patient orders	
4	Collect phlebotomy supplies and select a patient on the PDT list	
5	Scan the patient wristband to confirm positive patient ID - at the bedside	
6	Collect the specimens according to the order on the PDT	
7	Use the manual collection feature to identify the tube type	
8	Information is passed from the PDT to the portable printer	
9	Hollister label is completed by writing the patient name on the red wristband	
10	The phlebotomy is performed	
11	Hollister label is double signed by second RN to verify accuracy of patient/specimen/Hollister number	
12	Primary tubes are prepared for transport and sent to the lab	
13	PDT is docked into the cradle uploading all collection information to the system server subsequent to completed collection round	
14	Obtain patient consent for blood transfusion	
15	Obtain patient consent for blood transfusion	
16	Green blood requisition slip is sent with Transport to pick up blood product from Blood Bank.	
17	Vital signs taken by RN on transfusion patient prior to blood infusion.	
18	Blood is delivered and signed for by RN	
19	Two RNs (one the administering RN) check, and verify donor number, recipient name, blood type, expiration. Both sign transfusion slip.	
20	Blood is hung within 30 minutes of receipt	
21	RN to stay with patient five minutes monitoring for signs and symptoms. Vital signs every 15 minutes thereafter.	
22	Documentation recorded: (all must be present) a. Infusion time	

	b. End time c. No reactions d. Volume infused e. Final RN signature
23	Environment: Well lit
24	Environment: Free from clutter
25	Environment: Quiet
26	Cognitive Factors: Emotional variables
27	Cognitive Factors: Familiarity/certainty
28	Cognitive Factors: Bias (preconceived notions)
29	Human factors: Interruption
30	Human Factors: Distraction
31	Human Factors: Multitasking
32	Human Factors: Organizational skill
33	Human Factors: Followed workflow process

Analyses

Data analyses will be conducted using the Statistical Package for the Social Sciences (SPSS version 17.0 for Windows, Chicago, IL). Data for analyses came from existing data sets on latent errors as well as primary data collection, using the validated rule-based procedures that were developed as previously described. Appropriate procedures for each level of data were applied. Data analyses have been completed and reviewed by a qualified statistician.

The data were analyzed using the concepts derived from the human factors literature and the literature regarding errors in technology. The rule-based procedures for the observations were developed with items that define technologic steps and human factor items. Field note data were analyzed for recurring patterns (constant comparison) during each direct observation. The data were categorized according to themes identified. This information was used with the quantitative data analysis to:

- Revise and validate the rule-based procedures.
- Revise education curriculum as indicated.
- Integrate findings using appropriate hospital reporting structure.

Results

A total of 140 participants were consented for observation in this research. Thirty participants were consented for the specimen collection system and 119 observations were conducted. (See Table 4) One hundred and four participants were consented for bedside medication verification system and 284 observations were conducted. (see Table 5) Six participants were consented for the transfusion administration module and 34 observations were conducted (Due to small sample size, these data will not be presented)

Table 4 – Distribution of Characteristics Among 119 Observations in the Specimen Collection Evaluation

Factor	**N (%)**
Education Level	
PCA	113 (94.9%)
RN	6 (5.1%)
Age grouping (years)	
under 30	23 (19.3%)
30-34	38 (31.9%)
35-39	5 (4.2%)
40-44	38 (31.9%)
45 and up	15 (12.6%)
Professional Experience (years)	
0-2	22 (18.5%)
3-5	48 (40.3%)
6-10	33 (27.7%)
Greater than 10	16 (13.4%)
Experience at this facility (years)	
less than 1	3 (2.5%)
1-2	23 (19.3%)
3-7	71 (59.7%)
8-12	20 (16.8%)
13-20	2 (1.7%)
Primary work shift	
Days (7-3)	75 (63.0%)
Evenings (3-11)	32 (26.9%)
Nights (11-7)	10 (8.4%)
Extended Days (7-7)	2 (1.7%)

Table 5 - Distribution of Characteristics Among 284 Observations in EMAR Evaluation

Factor	**N (%)**
Education Level	
BSN	209 (73.6%)
Associate	70 (24.6%)
Diploma	2 (0.7%)
LPN	3 (1.7%)
Age grouping (years)	
under 30	40 (14.1%)
30-34	43 (15.1%)
35-39	57 (20.1%)
40-44	64 (22.5%)
45 and up	80 (28.2%)
Professional Experience (years)	
0-2	50 (17.6%)
3-5	45 (15.8%)
6-10	92 (32.4%)
Greater than 10	97 (34.2%)
Experience at this facility (years)	
less than 1	26 (9.2%)
1-2	41 (14.4%)
3-7	126 (44.4%)
8-12	44 (15.4%)
13-20	47 (16.5%)
Primary work shift	
Days (7-3)	94 (33.1%)
Evenings (3-11)	44 (15.5%)
Nights (11-7)	41 (14.4%)
Extended Days (7-7)	105 (37.0%)

Further analysis of the EMAR data demonstrated that there were variations in responses observed based on the age, years of experience and frustration level of the subject.

Table 6 – Relationship between ages, years of experience and frustration level

Age (years)	Experience (years)	Frustration Level		
		None	Moderate	High
Less than 30	0-2	25 (86.3%)	1 (3.4%)	3 (10.3%)
	3-5	9 (81.8%)	2 (18.2%)	0 (0.0%)
31-44	0-2	18 (76.2%)	2 (9.5%)	3 (14.3%)
	3-5	27 (93.1%)	2 (6.9%)	0 (0.0%)
	5-10	71 (82.6%)	10 (11.6%)	5 (5.8%)
	> 10	17 (60.7%)	9 (32.1%)	2 (7.1%)
45 and up	3-5	5 (100%)	0 (0.0%)	0 (0.0%)
	5-10	4 (66.7%)	2 (33.3%)	0 (0.0%)
	> 10	61 (88.4%)	8 (11.6%)	0 (0.0%)

The findings further revealed that this age group was consistently rated with the highest degrees of frustration over any other age groups in each of the codings. (Clutter, lighting, noise, distractions and interruptions) For the dimension of clutter, 22% of observations in the 31-44 age group were rated with high levels of frustration versus 0% in the 30 and below and 45 and above age groups. For situations in which there was minimal lighting, 50% of observations in the 31-44 age group were rated with high levels of frustration versus 0% in the 30 and below and 45 and above age groups. For situations where there was significant noise, 25% of observations in the 31-44 age group were rated with high levels of frustration versus 0% in the 30 and below and 45 and above age groups. For situations where there were at least 2 or 3 distractiosn during the observation, 40% in the 31-44 age group were rated with high levels of frustration versus 0% in the 30 and below and 45 and above age groups. And finally, for observations during which interruptions occurred, 37% in the 31-44 age group were rated with high levels of frustration versus 0% in the 45 and above group, whereas there was no difference between them and the 30 and under age group, where 33% were rated as frustrated.

Discussion

This study is a culmination of work beginning with developing a reliable system of occurrence reporting of medical errors within the organization to understand the magnitude and source of error. This guided the way to choosing vendors having a bar code technology or interest in developing such a technology. The engagement of the vendor with the clinical staff to streamline the process and establish and effective workflow was an arduous task. Choosing hardware that fit the user's needs and meet the needs of various clinical situations was a complex learning process.

The specimen collection system evolved from its beginnings as a unit based PC with print streaming to a central server, with bi-directional interfaces, wireless infrastructures and real time process. Each module was built from the ground up including, dictionary building, work flow maps, training manuals, and training simulation. Continuous hardware assessment has been an integral part of the evolution of this project as needs vary between patient care units as well as new hardware options that came onto the market and provide potentially, better solutions.

One significant departure from the original study design was the intent to deliver multiple clinical process applications on one pocket personal computer (pc). At the time of this study's conclusion, the vendor providing the bedside medication verification system could not support their software application on a pocket PC. As a result, pocket PC's were utilized for the specimen collection system and a variety of hardware applications were utilized for the bedside medication verification system. They include, stationary personal computers in patient rooms, laptop computers affixed to mobiles carts, COWS (computer on wheels) connected with wireless barcode scanners as well a C-5 tablets, with built-in barcode scanners, carried by hand. The main reasons for hardware variation was physical differences between building designs where patient care units reside and acceptance by the user for ease of adaptability.

The work demonstrated a 50% reduction in medication errors as a result of a failure of one of the 5 Rights to safe medication administration. (Right patient, drug, dose, route, and time) The specimen collection process demonstrated a reduction of error from 2% at the outset to the technology implementation to 0.025% at the conclusion of the study.

Observation and discussion revealed the explanation of 0.025% variance. 118 out of 120 observed users followed the steps in the user scenario as trained. 10 out of 120 observed users practiced a variation in the step of placing the label on the tube prior to collecting the next tube. This variation was observed only in the Emergency Department performed by patient care associates. The distribution of this process variation in the ED was statistically associated at a $p<0.05$. This further validates the recommendations of Croskerry and Sinclair to study the use of electronic clinical systems in the Emergency Department as noted in the Objectives section of this paper. One further opportunity for improvement in either the system design or in the rule based procedure is the failure in the step which allows the user to place the wrong label on the wrong collection tube.

The study further investigated the integration of user acceptance of the technology into their clinical process. Caregivers develop a reliance on their own personal workflow process which leads to their individual assurance of avoiding making mistakes. Introduction of a technologic replacement for their personal practice is not always well received. This study measured user acceptance in terms of degree of frustration with the technology and process relative to, environmental, cognitive and human factors defined as frequency variables. The findings showed a pattern of behavior relative to user age groups.

Users 35 and younger incorporated the technology into their practice with no frustration from the external frequency variables. Users 45 and older displayed a low to moderate degree of frustration when adapting to the technology. Data capture showed the highest statistical association with the age group 35-45 along with their years of professional experience relative to the highest frustration ratings. The principles of

generational differences suggest an explanation of the observations made in the study. Those in the 45 and older would be considered baby boomers. Characteristics used to describe baby boomers are, interest in learning new skills, workaholics, interested in participation and spirit in the workplace. Loyal employees.

The Generation X employee, typically between the ages of 25-45, watched their boomer parents, be workaholic loyal employees, be let go by their companies. Generation X people were typically latchkey kids, developed a great sense of self sufficiency. Their characteristics are self reliant, survivor mentality, wanting a balanced life. They grew up with information technology and multitask as a norm.

Observation and inquiry lead to this learning, which the users under 35 easily adapt to computer technology since they have been doing so all their lives. Any display of frustration was explained by the participant as lack of their professional experience in developing their clinical skills The technology was one factor they could count on in making their work more organized. (See Table 8)

Table 8 - Work Flow and Environment Issues from Observation Study

Factor	N (%)
Problem scanning patient's wristband	25 (8.8%)
Problem scanning dose	17 (6.0%)
Significant clutter in patient room	9 (5.3%)
Inadequate lighting	75 (26.4%)
Excessive noise	16 (5.6%)
Moderate to severe frustration	49 (17.3%)
Frequent interruptions	17 (6.0%)

Those over 45 explained that they recognize and embrace easily anything that is designed to help them provide safe practice which coincides with baby boomer mentality. Those in the 35-45 age group, the generation X people are used to multitasking and in as much as they vary in computer literacy based on being early or late generation X people, they experience the technology and the rule base procedure associated with it as cumbersome, complex and redundant. They look to be efficient beings by multitasking and have worked hard to strip away redundancy for efficiency and speed in accomplishing the task.

The trade off is the margin of risk with which the caregiver is working in. With the redundant steps stripped out of the process and given the right set of circumstances, such as multiple conflicting priorities, the caregiver doesn't recognize their high state of vulnerability for error. This is typically when errors occur. Under less stressed conditions, the caregiver skips redundant steps and no adverse outcomes occur, so their behavior is easily self justified. Like a self fulfilling prophecy, the development of this margin of risk in which they work happens over many years of practice without cognizance of it.

The conclusion drawn from this study is that the technology is not the sole element responsible for reducing the medical error. It is the integration of the user's willingness to understand the intent of the technology relative to their awareness of the margin of risk in which they are practicing. Once this is embraced, the user will follow the process as designed in the rule based procedures or adapt a process that conjoins safe practice with efficiency resulting in a reduction in medical error.

In order to maximize the impact of a medical error reduction initiative, an integrated approach including a technology as well as a culture of safety program has been proven successful. The strongest example of the successful co-existence of technology with clinical practice is in the specimen collection process. Being a development site for the specimen collection system enabled the end user to influence the vendor to make software design changes. The influence resulted in a technology process design that aligned most closely with the caregiver's thought process. This resulted in few workarounds and a very high rate of success, (99.975% accuracy).